

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
JOHN S. BEULICK
ARMSTRONG TEASDALE LLP
ONE METROPOLITAN SQUARE
SUITE 3600
ST. LOUIS, MO 63102

PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference 19502-2PCT		Date of Mailing (day/month/year) 18 FEB 2004 REPLY DUE within 1 months/days from the above date of mailing
International application No. PCT/US02/24525	International filing date (day/month/year) 02 August 2002 (02.08.2002)	Priority date (day/month/year) 02 August 2001 (02.08.2001)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A23L 1/05 and US Cl.: 426/573,578,575, 661		
Applicant PHAGIA-GEL TECHNOLOGIES, LLC		

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 02 February 2004 (02.02.2004)

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer N. Bhat Telephone No. 571-272-0987
---	---

Form PCT/IPEA/408 (cover sheet)(July 1998)

ENTERED
 Date: 2/24/04
 By: mcc
19502-2

WRITTEN OPINION

International application No.

PCT/US02/24525

I. Basis of the opinion

1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 pages 1-21, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the claims:
 pages 22-30, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the drawings:
 pages 1-2, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.
PCT/US02/24525

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Inventive Step (IS)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Industrial Applicability (IA)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 6, 16, 23, 26-27, 32-34, 43-48, 51-55

The opinion as to Novelty was negative (No) with respect to claims 1-5, 7-15, 17-22, 24-25, 28-31, 35-42, 49-50, 56-83

The opinion as to Inventive Step was positive (Yes) with respect to claims NONE

The opinion as to Inventive Step was negative (NO) with respect to claims 1-83

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-83

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

V. 2. Citations and Explanations:

Claims 1, 2, 7-12, 17, 24-25, 28-31, 35, 36, 42, 49, 50, 56, 64, 70 and 71 lack novelty under PCT Article 33(2) as being anticipated by Sheldon.

Sheldon teaches a thickened hydrolyte isotonic beverage wherein the beverage is thickened with a composition, which comprises water, carbohydrate, a modified food starch and various electrolytes and other minor ingredients. The beverage made as described by Sheldon is useful for persons having dysphagia or difficulty in swallowing. The beverage as provided includes providing a base, which includes a number of dry ingredients, which is then mixed with water, and then a base, which contains the modified food starch, which is used as the thickening agent for the beverage. The beverage is made from a dry concentrate of ingredients, which is admixed with water or can be diluted. Sheldon specifically teaches that the viscosity of the beverage can be controlled depending upon the application. [Note Column 2, lines 40-54] Although, Sheldon doesn't specifically make an aqueous thickening concentrate which is then added to a liquid the steps taught in Sheldon does provide making different bases and each base is admixed to provide a thickened hydrolyte isotonic beverage thus anticipating applicant's invention.

Claims 1- 5, 7-15, 17-22, 35-41 and 56-83 lack novelty under PCT Article 33(2) as being anticipated by Lee.

Lee teaches concentrated xanthan gum solution which can be admixed with other liquids as a thickener which can be used in foodstuff, cosmetics and pharmaceuticals applications. The aqueous concentrate includes xanthan gum as the thickening agent. The amount of xanthan gum used in the concentrated xanthan gum solution is within the range as taught by applicant. The xanthan gum solution can be stored and transported and has high clarity making it permissible to add to a beverage without clouding, the xanthan gum has high viscosity in dilute form. The concentrated xanthan gum is readily amendable to dilution with water and very effective as a thickening agent. [Note Column 6, lines 33-67 and Column 7, lines 27-40]

Claims 1-83 lacks an inventive step under PCT Article 33(3) as being obvious over Lee in view of Sheldon.

Lee teaches the invention substantially as claimed and teaches a process of making and aqueous xanthan gum concentrate which is readily amenable for dilution with other liquids as a thickener which can be used in foodstuff, cosmetics and pharmaceuticals applications. The aqueous concentrate includes xanthan gum as the thickening agent. The amount of xanthan gum used in the concentrated xanthan gum solution is within the range as taught by applicant. The xanthan gum solution can be stored and transported and has high clarity making it permissible to add to a beverage without clouding, the xanthan gum has high viscosity in dilute form.

However, Lee does not teach specifically using the xanthan gum concentrate in specifically thickening beverages and specific

WRITTEN OPINION

International application No.
PCT/US02/24525

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

beverages such as breast milk as claimed by applicant or that the thickened beverage is used in various medical treatments or for people suffering from dysphagia.

Sheldon teaches providing a thickened isotonic beverage thickened with a modified starch for persons suffering from dysphagia. The beverage as described by Sheldon is intended for hydration therapy. Lee teaches generically using a xanthan gum concentrate in aqueous solution to thicken the food or beverage, cosmetic or pharmaceutical teaching that the xanthan gum concentrate can be used as thickener in a number of applications thus to provide the xanthan gum concentrate in a beverage which can be used for various medical procedures or for dysphagia or can be added to soups, fluids, breast milk etc. would have been obvious to one having ordinary skill in the art.

Claims 1-83 meet the criteria set out in PCT Article 33(4) and thus has industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----